

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

<p>AVENTIS PHARMACEUTICALS INC., MARRELL PHARMACEUTICALS INC., and CARDERM CAPITAL L.P.,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>IMPAX LABORATORIES, INC., <i>et al.</i>,</p> <p style="text-align: center;">Defendants.</p>	<p>Civil Action Nos. 02-1322 (GEB) 03-1179 (GEB) 03-1180 (GEB) 03-5108 (GEB) 03-5829 (GEB) 04-1075 (GEB) 04-1076 (GEB) 04-1077 (GEB) 04-1078 (GEB) 04-2305 (GEB) 04-3194 (GEB) 05-4255 (GEB) 06-5463 (GEB) 07-5054 (GEB) 07-5180 (GEB) 09-0325 (GEB) 09-4638 (GEB) 09-5179 (GEB) 10-1471 (GEB)</p> <p style="text-align: right;"><b>MARKMAN OPINION</b></p>
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**BROWN, Chief Judge**

This matter comes before the Court on the parties' request for claim construction in a *Markman* hearing. The parties submitted their opening *Markman* briefs on September 2, 2010, and their responsive briefs on October 14, 2010. (Doc. Nos. 214, 215, 216, 219, 260, 262, 265, 267.)<sup>1</sup> The Court held a *Markman* hearing on November 10, 2010.

**I. Background**

This is a consolidated patent infringement case involving the pharmaceutical fexofenadine. Before the Court is the parties' request for claim construction in a *Markman* hearing. There are nine (9) patents at issue and twenty-nine (29) different disputed claim terms.

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<sup>1</sup> All docket citations are to the 09-4638 case because several of the other dockets do not contain every document that the parties submitted.

Three of the patents are the “Method Patents” – United States Patent Numbers 6,037,353 (the “‘353 patent”), 6,187,791 (the “‘791 patent”), and 6,399,632 (the “‘632 patent”). These patents share an identical specification and their claims are directed to administering fexofenadine to slightly different populations of people. Four of the patents are directed to fexofenadine formulations; these are United States Patent Numbers 6,039,974 (the “‘974 patent”), 5,855,912 (the “‘912 patent”), 6,113,942 (the “‘942 patent”), and 5,738,872 (the “‘872 patent”). The ‘942 and ‘912 patents share a written description. Finally, two of the patents are directed towards the process of making piperidine derivatives; they are United States Patent Numbers 7,390,906 (the “‘906 patent”) and 5,750,703 (the “‘703 patent”). These patents also share a substantially identical written description.

On November 10, 2010, this Court conducted a *Markman* hearing. At the hearing, the Court construed eleven (11) of the twenty-nine (29) terms for the reasons it set forth on the record. In addition to those eleven (11) terms, the parties agreed that three (3) terms from the ‘906 patents were no longer relevant to the asserted claims and conferred to arrive at a construction for the term “wet granulation” in the ‘872 patent. These rulings resolved all of the claim construction issues in the ‘353, ‘912, ‘942, and ‘872 patents. The Court reserved its ruling on the remaining fourteen (14) terms; these terms consist of all five (5) terms from the ‘791 and ‘632 patents, four (4) terms from the ‘974 patent, two (2) terms from the ‘703 patent, and three (3) terms from the ‘906 patent.

This opinion addresses only the four (4) outstanding terms in the ‘974 patent. The ‘974 patent is directed towards a bilayer pharmaceutical composition, each layer being made up of a separate formulation. (‘974 patent, 23:17-24:49.) The four (4) outstanding terms are “a suitable antiadherent,” “a suitable lubricant,” “a suitable glidant,” and “discrete zone.” (Joint Claim

Construction Chart (“JCC”) at 17-19, 22; Doc. No. 210-1.) The terms implicated in the ‘791, ‘632, ‘703, and ‘906 patents will be addressed in separate opinions.

## **II. Discussion**

### **A. Standard of Review**

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996). Claim construction, which serves this purpose, is a matter of law exclusively for the court. *Id.* at 979. Specifically, the focus of a court’s analysis must begin and remain on the language of the claims, “for it is that language that the patentee chose to use to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’” *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2).

Generally, there is a presumption that the words of a claim will receive the full breadth of their ordinary meaning. *NTP, Inc. v. Research In Motion, Ltd.*, 392 F.3d 1336, 1346 (Fed. Cir. 2004). The ordinary meaning may be derived from a variety of sources; including intrinsic evidence, such as the claim language, the written description, drawings, and the prosecution history; as well as extrinsic evidence, such as dictionaries, treatises, or expert testimony. *Id.*

When determining the meaning of the terms, the court must give primary consideration to the intrinsic evidence, including the specification. The specification “is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1587 (Fed. Cir. 1996). However, it is improper to import limitations from the specification to the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320, 1323 (Fed. Cir. 2005); *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1364-65 (Fed. Cir. 2003). In addition to the intrinsic evidence,

a court may also consider extrinsic evidence when an analysis of the intrinsic evidence alone does not resolve the ambiguities of a disputed claim term. *Vitronics Corp.*, 90 F.3d at 1582-83.

The presumption of ordinary meaning may be rebutted if the patentee acted as his or her own lexicographer by clearly setting forth a definition of the claim term unlike its ordinary and customary meaning. *Brookhill-Wilk I, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298-99 (Fed. Cir. 2003). The patentee's intent to define the term must be clear before the court will use it to redefine the term and impose limits on the ordinary meaning. *Merck & Co, Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005). Indeed, the Federal Circuit has "repeatedly encouraged claim drafters who choose to act as their own lexicographers to clearly define terms used in the claims in the specification." *Sinorgchem Co. v. ITC*, 511 F.3d 1132, 1136 (Fed. Cir. 2007).

When the patentee has not provided an explicit definition of a claim term, the words of a claim are given their plain and ordinary meaning to a person of ordinary skill in the art. *Vitronics*, 90 F.3d at 1582. The person of ordinary skill in the art is deemed to have read the claim terms in the context of the entire patent, including the specification. *Phillips*, 415 F.3d at 1313.

## **B. Analysis**

### ***1. A suitable antiadherent***

Plaintiffs propose that "a suitable antiadherent" should be construed to mean "an ingredient in a pharmaceutical formulation appropriate for reducing sticking or adhesion of any of the tablet granulation or powder to the faces of the punches or to the die wall." (JCC at 17; Doc. No. 210-1.) Defendants propose that the term means "stearic acid, cetyl alcohol, stearyl

alcohol, paraffin, white wax, glycerin, lanolin, talc or similar compound performing the same function in the context of the formulations described in the patent.” (*Id.*)

The difference between the constructions is that Defendants’ construction defines the term by way of examples that are set forth in the specification and then includes “compound[s] performing the same function in the context of the formulations described in the patent” whereas Plaintiffs have created a construction from treatise and dictionary definitions that they suggest reflect the ordinary meaning of the term. (JCC at 17; Doc. No. 210-1.) The Court does not adopt either construction.

Construction of this term requires the Court to examine three issues: (1) whether the specification clearly defines the term “suitable antiadherent”; (2) whether the word “suitable” acts as a limit on the claim term “suitable antiadherent”; and (3) if the word “suitable” is a limitation, the Court must determine the proper meaning to assign to the term. The Court finds that the specification does not define the term “suitable antiadherent,” that the plain meaning of the term requires that the word “suitable” limit the word “antiadherent” to fewer than all antiadherents, and that “suitable” refers to antiadherents that successfully produce the product in the claims without suffering from the problems presented in the patent’s discussion of the prior art.

*a. Issue 1: The specification does not define “suitable antiadherent”*

Turning to the first issue, the specification does not define the term “suitable antiadherent.” Defendants’ construction is similar to the language of the specification, which states:

As used herein, the term “suitable antiadherent” includes stearic acid, cetyl alcohol, stearyl alcohol, paraffin, white wax, glycerin, lanolin, talc, mineral oil and the like. The preferred suitable antiadherent is stearic acid.

(‘974 patent, 10:1-4.) The question raised by this passage is whether it defines the term.

This passage does not define the term because such lexicography must be clear and explicit and this language does not use a defining transition phrase like those used by other terms that are defined in the patent. This language says that a “‘suitable antiadherent’ *includes*[.]” (‘974 patent, 10:1.) This is not a clear definition transition phrase like “defined as” or “means” or “refers to” or “is,” which other terms in the specification use. (*See* ‘974 patent, 7:51-10:25, 4:58-65.) When the patentee meant to clearly define the term, he did so by using a transition phrase that unambiguously imparted a definition. Thus, despite the fact that the language includes the statement “as used herein” and puts quotation marks around “suitable antiadherent,” the lack of a transition phrase that indicates a definition prevents the term from being clearly redefined. *Merck & Co*, 395 F.3d at 1370 (redefinition of a term must be clear).

However, this passage does give examples of antiadherents that must be included in the term, and requires other antiadherents to be in some way similar to those listed (though it leaves out how they should be similar). Thus, the Court will include these examples as part of the construction, because while the specification does not give guidance on which additional antiadherents would qualify, it at least makes clear that the listed antiadherents fall within the definition. This provides some additional clarity for the Court in assessing the meaning of the terms.

While the Court adopts these examples as part of the definition, the Court cannot adopt Defendants’ construction, which in addition to these examples only includes “similar compound[s] performing the same function in the context of the formulations described in the patent.” Defendants’ construction does not mention that any additional compound must be an

antiadherent and gives completely no guidance as to which additional compounds would be “suitable antiadherents.” Specifically, Defendants’ construction is

stearic acid, cetyl alcohol, stearyl alcohol, paraffin, white wax, glycerin, lanolin, talc or similar compound performing the same function in the context of the formulations described in the patent.

(JCC at 17; Doc. No. 210-1.) This construction merely lists the examples in the patent, and then extends them to “similar compounds” without even mentioning that what each example has in common is that it is an antiadherent. This is like interpreting a term “rocks such as granite, shale, and sandstone” to mean “granite, shale and other materials that perform the same function.” That construction gives no indication that what unites the examples is that they are rocks and Defendants’ construction similarly does not explain that what unites the examples is that they are antiadherents. Thus, the Court must include some reference to the fact that any additional compound must be an antiadherent.

The Court includes Plaintiffs’ definition of “antiadherent” because Defendants agreed at the *Markman* that it accurately described the meaning of the term in the art and its use in the patent; their dispute was the definition of a “suitable antiadherent.” However, while including the definition of antiadherent assists the Court in tying together the examples, it does not assist with the meaning of “suitable.”

*b. Issue 2: “Suitable” limits the antiadherents that are claimed*

Addressing the second issue, the word “suitable” does act as a limit on the term. The ordinary meaning of the term “suitable antiadherent” shows that not every antiadherent or even every pharmacologically acceptable antiadherent meets the requirements; that antiadherent must also be “suitable.” Plaintiffs’ definition reads the term “suitable” out of the term because it

simply requires that a suitable antiadherent be “appropriate” for the very purpose that an antiadherent serves.

Plaintiffs’ construction is a composite of treatise and dictionary definitions of the word “suitable” and the word “antiadherent.” (JCC at 17; Doc. No. 210-1.) Specifically, Plaintiffs cite the ordinary meaning of “suitable” as meaning “appropriate” (Pls.’ Br. at 35; Doc. No. 215) and “antiadherent” as “an ingredient in a pharmaceutical formulation which reduces sticking or adhesion of any of the tablet granulation or powder to the faces of the punches or to the die wall.” (JCC at 17; Doc. No. 210-1.) Any compound appropriate for these purposes is already included in the definition. Any compound that “reduces sticking or adhesion of any of the tablet granulation or powder to the faces of the punches or to the die wall” would also be “appropriate” for reducing that sticking. It would not be possible to name an antiadherent that was not “appropriate” for these purposes because then it would not be an antiadherent. Thus, defining “suitable” as “appropriate” for antiadherent purposes makes the term “suitable” superfluous. The ordinary meaning of the term requires a narrower interpretation.

Therefore, Plaintiffs’ construction is incorrect because it reads the word “suitable” out of the claim term, and thus impermissibly broadens the term’s meaning. *See Exxon Chem. Patents v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995) (each word is important and cannot be read out of the claim term); *see also Fujitsu Ltd. v. Netgear Inc.*, 2010 U.S. App. LEXIS 19543 (Fed. Cir. Sept. 20, 2010). The Court then, adopts a construction that properly uses “suitable” as a limitation on the term, in line with the term’s ordinary meaning.

*c. Issue 3: “Suitable” refers to success in producing the patented product and avoiding the pitfalls of the prior art*

The Court finds that the limit the specification places on antiadherents by requiring them to be “suitable” references the problems that this patent solves in the art. Very little direct



information is available in the specification or the prosecution history for the meaning of this term. Thus, after looking for other measures of suitability in the patent, the Court concludes that the only plausible standard set forth is that “suitable” means that the antiadherent is suitable for producing the invention and fulfilling some advantages of the patented process over the prior art.

Other than the passage quoted above, no portion of the patent gives direct guidance on the meaning of the term “suitable antiadherent.” Indeed, the word “suitable” cannot mean “pharmaceutically acceptable” as Plaintiffs suggest because when the patent means “pharmaceutically acceptable” it explicitly uses those words. (*See* ‘974 patent at 7:51-8:14 (defining a “pharmaceutically acceptable salt”).) Thus, if the patentee had meant “pharmaceutically acceptable,” he would have used that term like he did in other areas of the patent. *See Acumed v. Stryker*, 483 F.3d 800, 807 (Fed. Cir. 2007) (finding that “transverse” did not mean the same thing as “perpendicular,” because if it did, there would have been no need to use both terms).

Defendants’ proposed construction also does not properly interpret “suitable” because it improperly limits the claim term. Defendants’ construction requires that to be suitable, the antiadherents must behave similarly with respect to the “formulations described in the patent.” (JCC at 17; Doc. No. 210-1.) However, these formulations are simply embodiments and examples, and do not encompass all formulations that would be part of the patent. Thus, interpreting the term in this way would break the cardinal rule of claim interpretation by importing limitations from the specification into the claims. *Phillips*, 415 F.3d at 1320, 1323.

Without other options in the intrinsic evidence,<sup>2</sup> the Court finds that suitable antiadherents are those that successfully solve the problems identified in the patent’s discussion of the prior art to arrive at the solution of the patent. The patentee likely meant that the

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<sup>2</sup> The patents “Examples” all use antiadherents in the list.

antiadherent worked for the purposes of the invention. While the patent cannot be limited to the problems and particular solutions disclosed in the Background of Invention, there can be no dispute that an antiadherent that can create a formulation complying with those improvements is a “suitable antiadherent.”

The Background of the Invention mentions several drawbacks of previous formulations and their solution by the current formulation. (‘974 patent, 1:10-2:14.) These include problems with the “chemical degradation of the piperidinoalkanol in the presence of ibuprofen,” failure due to “unexpected and unacceptable cracking and unacceptable physical strength of tablets on final compression,” and failure because “some of the samples . . . did not meet United States Pharmacopeia (USP) requirements.” (*Id.*) Ultimately the inventors identified these objects and results of the invention:

An object of the present invention is to provide a pharmaceutical composition in oral dosage form as a bilayer tablet which provides immediate release of piperidinoalkanol compound and sustained release of sympathomimetic drug that exhibits acceptable bioavailability of each compound. An additional object of the invention is to provide a pharmaceutical composition in bilayer tablet form of high integrity consisting of an immediate release form of piperidinoalkanol compound and sustained release form of a sympathomimetic drug, such that the tablet resists cracking on standing, has acceptable physical strength and provides acceptable content uniformity which meets USP requirements. A further object of the present invention is to provide a bilayer tablet which exhibits a dissolution profile of the piperidinoalkanol which is similar to that of ALLEGRA® 60 mg capsules and a dissolution profile of sympathomimetic drug which is slower than that of SUDAFED® 120 mg tablets.

A novel pharmaceutical composition in the form of a bilayer tablet has now been found which provides efficient and immediate absorption, and bioavailability of a piperidinoalkanol, such as 4-[4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-1-hydroxybutyl]- $\alpha,\alpha$ -dimethylbenzeneacetic acid hydrochloride, and efficient sustained release and bioavailability of a sympathomimetic drug, such as pseudoephedrine hydrochloride after oral administration thereof. In addition, the novel bilayer tablet of the present invention exhibits acceptable content uniformity under USP requirements, resists cracking on standing and has acceptable physical

strength. Furthermore, the novel bilayer tablet of the present invention provides a dissolution profile of 4-[4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-1-hydroxybutyl]- $\alpha$ ,  $\alpha$ -dimethylbenzeneacetic acid hydrochloride which is similar to that for ALLEGRA® 60 mg capsules and a dissolution profile for pseudoephedrine hydrochloride which is slower than that for SUDAFED 12 HOUR® 120 mg tablets.

(‘974 patent, 2:13-50.) Thus, an antiadherent that is part of a formulation that fulfills these objects would be a “suitable antiadherent.” This definition may be further developed as the case progresses and evidence is presented that further defines or identifies other “suitable antiadherents.”

Thus, because “suitable” does limit the antiadherents that satisfy the claim term and “suitable” refers to the antiadherent’s usefulness in producing the claimed invention and meeting its objects, the Court construes “a suitable antiadherent” to mean “stearic acid, cetyl alcohol, stearyl alcohol, paraffin, white wax, glycerin, lanolin, talc or any similar compound that performs the same function by reducing adhesion of any of the tablet granulation or powder to the faces of the punches, or to the die wall, and by acceptably producing the claimed formulation while fulfilling the advantages of the invention over the prior art.”

## 2. “A suitable lubricant,” and “a suitable glidant,”

The parties agreed that these two terms involve almost identical issues as those presented above. The patent presents them in the same manner – with lists of examples and without additional guidance. Thus, the Court will construe them in a manner consistent with the above discussion.

## 3. “Discrete zone”

Plaintiffs propose that this term should be construed to mean “a separate region, including for example a separate layer.” Defendants propose that this term should be construed

to mean “a zone that is individually separate and distinct from another zone, each zone being a compressed granulation.” (JCC at 22; Doc. No. 210-1.)

These constructions are more similar than the parties intimate. The primary differences are that Defendants’ construction requires that each distinct zone is compressed individually and that each zone is a “granulation.” The Court will address both of these differences below. The remaining difference, between “individually separate” and “separate” is ephemeral; these words differ only in that “individually separate” is redundant.

*a. Whether the zones must be compressed individually*

The intrinsic evidence reveals that the discrete zones must be “compressed together” and not individually compressed. Both parties rely on the same sections of intrinsic evidence: the claims themselves and one passage from the specification. The claims themselves simply state that there are two discrete zones made up of different formulations. (’974 patent, 23:18-45.)

The parties also cite the specification during its definition of a different term, “layered tablet”:

As used herein a layered tablet is a tablet which is made up of two or more distinct layers or discrete zones of granulations compressed together with the individual layers lying one on top of another. Such conventional layered tablets are *generally* prepared by compressing a granulation onto a previously compressed granulation. The operation may be repeated to produce multilayered tablets of more than two layers.

(’974 patent, 11:3-6) (emphasis added.) This section does speak of the two layers being “compressed” and says that *generally* the first is compressed and then each subsequent granulation is compressed onto a previous one. However, Defendant’s construction does not comport with this passage because it implies that *each* zone be compressed individually, rather than to be compressed together as the specification sets forth. Thus, the zones should not be limited to being compressed individually as there is no support for this construction in the intrinsic evidence.

*b. Whether the zones must be granulations*

The specification does require the discrete zones to be granulations because it requires a bilayer tablet to have discrete zones that are granulations. “Bilayer tablet” is contained in the claim preamble, which normally does not limit the claim. However, because it recites limitations of the claim or is necessary to give meaning to the claim, it acts as a limit on the remaining portion of the claim. Thus the limitation that discrete zones be granulations that is contained in the meaning of “bilayer tablet” properly limits the meaning of “discrete zones.”

First, as the Court found in the *Markman* hearing, “bilayer tablet” limits the claim language. Preliminarily, the Court notes that neither of Plaintiffs’ briefs argued to the contrary; rather, Plaintiffs proposed a construction for the term and it was only at the Markman hearing that counsel mentioned that a preamble does not limit the claim terms. (*See* Pls.’ Br. at 43-44; Doc. No. 215; Pls.’ Resp. Br. at 37-39; Doc. No. 267.) That argument is properly deemed waived. However, even if it was not, the preamble limits the claim.

A phrase in a preamble usually does not act as a limit on a complete claim. However, if “the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed” to limit the claim. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1246 (Fed. Cir. 2008.) For example, in *Computer Docking Station v. Dell*, 519 F.3d 136 (Fed. Cir. 2008), the court found that the preamble terms “portable computer” and “portable computer microprocessing system” limited the scope of the claims. The court relied on the fact that the terms clearly recited a necessary and defining aspect of the invention—its portability. *Id.* at 1375. Further, the court found that the specification and the prosecution history emphasized that portability was an important aspect of the invention. *Id.*

Here, as in *Dell*, the term “bilayer tablet” recites important defining aspects of the invention. The patentee describes the two-layer nature of the invention in the Summary of the Invention. (‘974 patent, 2:53-55, 3:19-20, 4:1-2.) This is reflected in the Background of the Invention as well. (‘974 patent, 2:30-50.) Thus, the term “bilayer tablet” gives life, meaning and vitality to the claim, which does not otherwise require only two layers. *See Halliburton*, 514 F.3d at 1246. Thus, its importance in imparting this limitation, combined with the fact that Plaintiffs’ did not contest its limiting nature, supports the Court’s finding that the term “bilayer tablet” limits the claim terms.

Second, the limits of the term “bilayer tablet” require that the “discrete zone” be a granulation. While “bilayer tablet” is not itself defined in the specification, a term that encompasses it, “layered tablet” is defined in the specification. Thus, because the genus “layered tablet” is defined, any limitations on that term would apply equally to the species “bilayer tablet.”

“Layered tablet” is clearly defined in the specification, which states

As used herein a layered tablet is a tablet which is made up of two or more distinct layers or discrete zones of granulation compressed together with individual layers lying one on top of another. Layered tablets have the appearance of a sandwich because the edges of each layer or zone [are] exposed. Such conventional layered tablets are generally prepared by compressing a granulation onto a previously compressed granulation.

(‘974 patent, 11:3-12). This uses a clear defining transition phrase and the words “as used herein”; both of these show that that the patentee intended a definition. Thus, as described by the definition, both a “layered tablet” and a “bilayer tablet” must have “discrete zones of granulation compressed together with individual layers lying one on top of another.” Therefore, the “discrete zone” must be made up of “*granulation* compressed together with the individual layers lying one on top of another.”

Therefore, because the term “bilayer tablet” limits the scope of the claims, and because the specification requires the bilayer tablet’s “discrete zone” to be made up of granulations, the Court construes “discrete zone” to mean “a separate region of granulation, including for example a separate layer.”

### **III. Conclusion**

For the reasons set forth above, the Court construes “a suitable antiadherent” to mean “stearic acid, cetyl alcohol, stearyl alcohol, paraffin, white wax, glycerin, lanolin, talc or any similar compound that performs the same function by reducing adhesion of the tablet granulation or powder to the faces of the punches, or to the die wall, and by acceptably producing the claimed formulation while fulfilling the advantages of the invention over the prior art”; “a suitable lubricant” to mean “magnesium stearate, calcium stearate, zinc stearate, stearic acid, talc, hydrogenated vegetable oil or any similar compound that performs the same function by reducing the friction during tablet ejection between the walls of the tablet and the walls of the die cavity in which the tablet was formed and by acceptably producing the claimed formulation while fulfilling the advantages of the invention over the prior art”; “a suitable glidant” to mean “silicon dioxide, talc or any similar compound that performs the same function by promoting flow of the tablet granulation or powder material by reducing the friction between the particles and by acceptably producing the claimed formulation while fulfilling the advantages of the invention over the prior art”; and “discrete zone” to mean “a separate region of granulation, including for example a separate layer.”

Dated: January 11, 2011.

/s/ Garrett E. Brown, Jr.  
GARRETT E. BROWN, JR., U.S.D.J.